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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,334

12/30/2004

Mitsuru Maeda

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07/31/2006

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/500,334

Applicant(s)

MAEDA ET AL.

Examiner

Traviss C. McIntosh

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-25 is/are pending in the application.
- 4a) Of the above claim(s) 16-20,23 and 24 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,8 and 11-13 is/are allowed.
- 6) ☒ Claim(s) 2,5-7,9,10,14,15,21,22 and 25 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/19/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed April 19, 2006 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 2, 5-7, and 10-22 have been amended.

Claims 24-25 have been added

Claims 3-4 have been canceled.

Remarks drawn to rejections of Office Action mailed 10/19/2005 include:

Claim objections: which have been overcome by applicant's amendments and have been withdrawn.

112 2nd paragraph rejections: which have been overcome in part by applicant's amendments and have been withdrawn in part.

102(b) rejection: which has been overcome by applicant's amendments and has been withdrawn.

An action on the merits of claims 1-2 and 5-25 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Election/Restrictions

Newly submitted or amended claims 16-20 and 23-24 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: there were no methods of treatment present in the originally examined claims, and these claims are drawn to a new class of inventions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-20 and 23-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Claims 5-7, 9, 10, 14-15, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 5 is indefinite wherein the claim is drawn to a method of producing 2-O-(β -D-glucopyranosyl) ascorbic acid comprising immersing a plant in solvent to obtain an extract, but these steps are not seen on how to make a compound, but rather how to prepare an extract. The claim is not include sufficient methodological steps to afford the skilled artisan on how to make the claimed products. Methods of making compounds must include the steps necessary to perform the process.

Claims 6, 7, and 25 depend from claim 5 and fail to add any methodological steps to the method of claim 5, and thus are rejected for the same reasons is claim 5 above.

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Claim 9 is indefinite wherein the claim provides that the R groups of formula (2) are acetyl groups, however, the R groups cannot be acetyl groups as R is limited to C₁₋₅ alkyl groups. It is believed applicants intended the R groups together with the attached C=O group are acetyl groups, as acetyl groups are known to be -C(O)CH₃ groups. Applicants can amend the claim to read as: “wherein all of the R groups in formula (2) together with their attached C=O group, are acetyl groups”, or “wherein all of the R groups of formula (2) are methyl”, as both would provide for acetyl groups attached to the exocyclic 2', 3', 4', and 6' oxygens on the saccharide.

Claim 10 is drawn to methods of producing 2-O-(β-D-glucopyranosyl) ascorbic acid using a tetra-acyl derivative as an intermediate, but fails to set forth any actual methodological steps to be used in the process. Methods of making compounds must include the steps necessary to perform the process.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).

Claim Rejections - 35 USC § 102

Newly amended claims 2, 14, and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 07252160 ('160 patent).

Claim 2 is drawn to an extract of *Lycium chinense* comprising 2-O-(β-D-glucopyranosyl) ascorbic acid. Claim 14 is drawn to a composition comprising 2-O-(β-D-glucopyranosyl) ascorbic acid and a pharmaceutically, cosmetically, or dietarily acceptable component. It is noted that the methods of making the compound as set forth in claim 14 are of no patentable import.

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Claim 21 is drawn to a pharmaceutical or cosmetic composition comprising 2-O-(β -D-glucopyranosyl) ascorbic acid and a pharmaceutically or cosmetically acceptable carrier. Claim 22 is drawn to a pharmaceutical or cosmetic composition comprising the provitamin C extract of claim 2 and a pharmaceutically or cosmetically acceptable carrier.

The '160 patent discloses alcohol extracts of *Lycium Chinese*. It is noted that the extracts of the instant application are also alcohol extracts, therefore, absent evidence to the contrary, the examiner believes the extract of the '160 patent must comprise the 2-O-(β -D-glucopyranosyl) ascorbic acid. The '160 patent also discloses extracts with subsequently added sugar, which is a dietarily acceptable component and a pharmaceutically acceptable carrier. The extracts of the '160 patent are seen to anticipate the extracts and compositions of claims 2, 14, and 21-22 of the instant application.

Allowable Subject Matter

Claims 1, 8, and 11-13 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or fairly suggest the compounds of claims 1, 8, and 9 of the instant application. The prior art teaches of 2-O-(α -D-glucopyranosyl) ascorbic acid (note the alpha conformation) as vitamin C prodrugs (see US 5,407,812), but also teaches that β -derivatives cannot be decomposed in the body and are therefore not useful (see Japanese unexamined patent publication HEI no. 3-13599). As such, one of skill in the art would not have expected the β -derivatives to have efficacy as therapeutic agents.

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Moreover, it is noted that if applicants are interested in obtaining composition claims comprising the allowable compounds, applicants are encouraged to draft the claims in a manner similar to the following: a composition comprising 2-O-(β -D-glucopyranosyl) ascorbic acid in an amount ranging from 0.1-30 wt% and a pharmaceutically, cosmetically, or dietarily acceptable component. This provides the identity of the active agent, the amount of the active agent, and a secondary agent, which is not seen to be taught or fairly suggested in the prior art. Moreover, it is noted that the range of 0.1-30 wt% is taken from applicant's specification, page 25, example 6.

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. McIntosh
July 21, 2006


Shaojia A. Jiang
Supervisory Patent Examiner
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